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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/769,118

01/29/2004

Shu-Wen Fu

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

07/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/769,118

Applicant(s)

FU ET AL.

Examiner

Kevin E. Weddington

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 32-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1-29-04</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 1-56 are presented for examination.

Applicants' information disclosure statement filed January 29, 2004 has been received and entered.

Applicants' election filed July 5, 2007 in response to the restriction requirement of June 6, 2007 has been received and entered. The applicants elected the invention described in claims 1-31 (Group I) without traverse.

Claims 32-56 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7-9, 14, 15, 18, 23-25, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Janoff et al. (5,616,344) of PTO-1449.

Janoff et al. teach a drug-lipid complexes association with hydrophobic drugs such as amphotericin B and with phospholipids such as dimyristoylphosphatidylcholine (DMPC) and dimyristoylphosphatidylglycerol (DMPG) (see the abstract). Note particular to column 6, lines 44-45 states the drug molar ratio amount is greater than 5 mol %, this range anticipates applicants' molar ratio of the drug-lipid of 1:9 to 9:1. Note column 9, lines 1-6 teaches the phospholipids molar ratio between dimyristoylphosphatidylcholine (DMPC) and

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dimyristoylphosphatidylglycerol (DMPG) is from about 99:1 to about 1:99, and applicants' molar ratio of 4:1 to 2:1 falls within the range. Note column 9, lines 33-65 show other hydrophobic drugs are also used in this drug-lipid complex. Note column 14, lines 62-63 teaches grinding the mixture with "a mechanic means" such as a colloid mill. Also note Example 11 teaches the water solubility of amphotericin B is 0.1 mg/ml, which is less than 10 mg/ml, set forth in applicants' invention.

Clearly, the cited reference teaches every limitation of the instant invention; therefore, the instant invention is unpatentable.

Claims 1, 2, 7-9, 14, 15, 18, 23-25, 30 and 31 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janoff et al. (5,616,333) of PTO-1449 in view of Verhoff et al. (6,604,698 B2).

Janoff et al. were discussed supra for a drug-lipid complex comprising a drug and one or more phospholipids and grinding the mixture with a mechanic means.

The instant invention differs from the cited reference in that the cited reference does not teach the drug-lipid complex has a particle size of 60-6,000 nm. However, to determine various particle sizes of the drug-lipid complex having optimum effectiveness is well within the level of one having ordinary skill in the art, and the skilled artisan would have been motivated to determine any particle size would give the same maximum effectiveness in the absence of evidence to the contrary.

The instant invention differs from the cited reference in that the cited reference does not teach the applicants' preferred mechanic means is a dispersion

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mill such as a ball mill. However, the secondary reference, Verhoff et al., teaches media mills such as ball mill are well-known in the art for drug-lipid complexes.

Clearly, to substituted colloid mill as a mechanic means to grinding the drug-lipid complexes into particles with a ball mill would have been obvious those skilled in the art since the outcome will achieve the same end product in the absence of evidence to the contrary.


Claims 1-31 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm-9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
July 12, 2007